tcs ADD™

Building on belief

TCS ADD™ Connected Clinical Trials

Bringing continued innovative pharmaceutical products to the market in the future will demand improvements in the clinical trial process, including personalized engagement with trial participants, high-quality data capture, effective patient monitoring, and increased operational efficiencies – aspects that are key to the incorporation of decentralized clinical trials.

With these goals in mind, Tata Consultancy Services (TCS) has developed a comprehensive decentralized trials suite of platform - the TCS ADD™ Connected Clinical Trials (CCT). This modern, scalable, and modular platform can be used by pharmaceutical companies to significantly transform the way clinical trials are conducted today– making them patient-centric, site friendly, and 'digital by default.'

The platform integrates with various smart technologies, alleviating the burden on patients and sites, and enables decision making by investigators and sponsors in real time. The desired result is complete transparency, increased patient engagement, improved medication adherence, efficient trial supplies, and a highly automated clinical trial process.

Overview

Digital technologies are increasingly being embedded in the daily lives of patients and on-site but are not yet integrated seamlessly into trials. Because of this, participating in clinical trials is often cumbersome, providing inefficient patient-engagement and achieving compliance with protocols sometimes becomes difficult. Pharmaceutical companies are striving to reduce the trial timelines to bring drugs to patients in need faster and are seeking new ways to facilitate adaptive trial designs and combine multiple studies. At the same time, regulatory requirements for patient health and data quality are increasingly becoming stringent, forcing pharmaceutical companies to rethink manual, paper-based, time-consuming and error-prone processes of managing clinical supplies.

The TCS ADD™ CCT platform aims to connect patients, sites, and sponsors —key stakeholders in any clinical trial with a variety of innovative sensors, smart medication packages, and mobile devices. CCT enables the collection of patients' health outcomes using mobile apps, wearables, engagement tools, and smart, connected devices, thereby reducing the need for site visits and making the trials more accessible to patients. With real-time data integration, analytics, and tailored patient support, CCT is designed to foster seamless connection between patients, sites, and sponsors and is intended to ensure full compliance to regulatory norms.

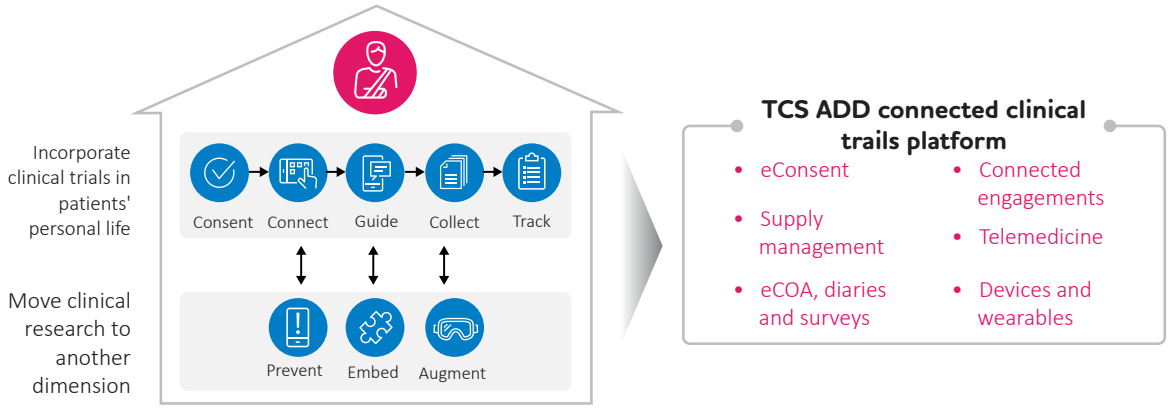

Figure 1: Schematic Overview of the TCS ADDTM Connected Clinical Trials platform

Our solution

TCS ADD™ Connected Clinical Trials Platform Offerings:

- Supply Management
  - **Kit tracking:** Automated and real-time tracking and verification (e.g. receipt, processing, handout, and return) of kits accessible via site portal/site app supporting direct-to-patient and traditional supply models
  - **Digital label:** Personalized, easily accessible digital label and label updates in patient's preferred language delivered via patient app and site app/portal
  - **Pill/Unit dose tracking:** Automated and real-time tracking of individual pill/unit dose intake via sensor-enabled packages (barcode, NFC, Bluetooth) and accessible via site portal/app and patient apps

- **eConsent –** Patient-centric, flexible, and secure end-to-end informed consent solution with advanced digital experience
- **eCOA , diaries and surveys -** Unified, fast, and one-click approach to data collection and oversight for patients, sites, and sponsors, either entered electronically or uploaded in the paper form
- **Telemedicine -** Seamless and feature-rich audiovisual interaction between patients, sites, and sponsors across web and mobile apps
- **Devices and wearables -** Biometric sensors with connected medical devices for timely and accurate health insights through automated data collection and remote monitoring
- **Connected engagements -** Personalized patient and site support throughout the trial process via portals, apps, and multimedia literature

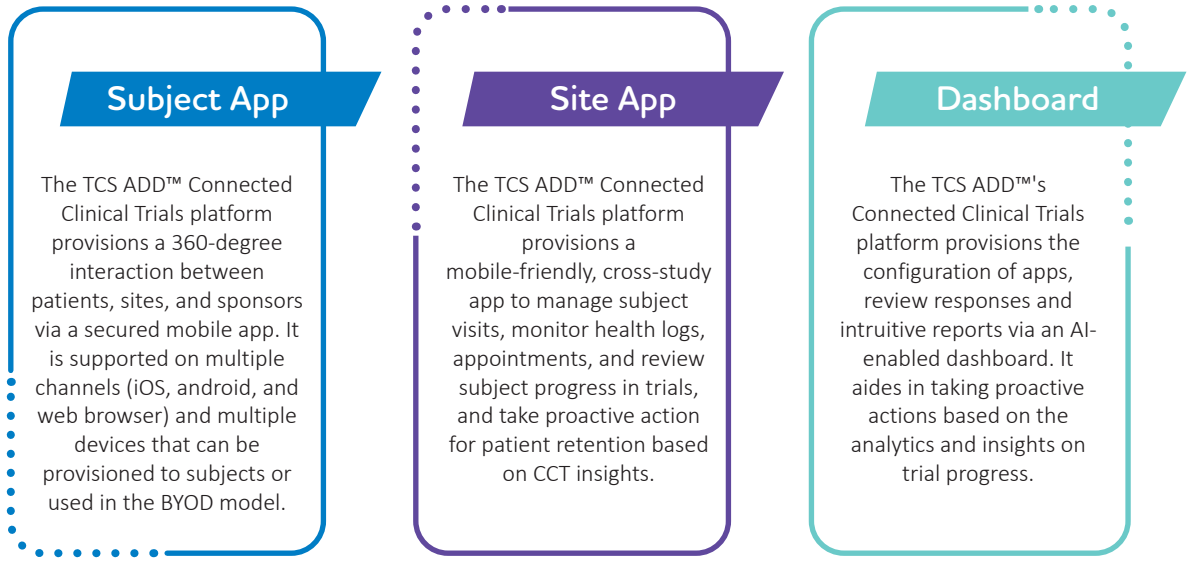

Figure 2: Key components of the TCS ADD™ Connected Clinical Trials platform

Benefits

The TCS ADD™ CCT platform has been developed in close collaboration with pharma and multidiscipline stakeholders (Clinical, regulatory, supply chain, privacy etc) putting the patient at the center. Pilot feedback, collected from patients and sites via surveys and interviews, have been taken into consideration while enhancing this platform. All efforts have been considered so that the CCT platform may enable pharmaceutical and bio-pharmaceutical companies to realize the following benefits::

Increased efficiencies and reduced workload

- Up to 50% reduction in dropouts linked to drug or protocol non-compliance
- Up to 30% reduction in eCOA cost due to device non-provisioning
- Increased site response to feasibility questionnaires and higher subject study participation and compliance due to integrated services
- Up to 80% reduction in on-site drug monitoring activities, data entry, and reconciliation
- Up to 100% reduction in wrong kit dispensing and high reduction in drug waste
- Up to 50% reduction in drug non-compliance related dropouts

Enhanced data quality and oversight

- Up to 60% reduction in drug-related inspection / audit activities
- Up to 5% reduction in data management queries related to drug accountability
- Reduced consent-related audit findings such as missing names, etc.

Meaningful insights and prevention

- Behavioral insights to predict dropouts and non-compliance
- Reminders to keep patients engaged throughout the study duration
- Direct insights into medication intake and behavioral changes at home
- Potential to develop drug medication intake models and novel insights

Increased patient and site engagement

- Increased understanding and access to complete drug information
- Reduced administrative burden and increased patient safety
- Higher patient engagement due to personalized, easy-to-understand study information
- Enhanced site engagement with a single, unified solution

Quicker go/no-go decisions - Reduced assumptions of actual medication intake enabling faster decision making to continue with a compound

Faster drug registration process - Ability to combine individual studies, support adaptive trial designs, and alter medication intake on-the-go

The TCS advantage

With CCT, you will be able to explore the use of the following differentiators:

Developed for industry needs:

- Developed in alignment with cross-industry initiatives and outputs from ISPE, DTRA, TransCelerate, and such organizations
- Face-to-face workshops and events with industry-wide stakeholders from trial sponsors, medication and technology suppliers, patients, and sites
- Thought leadership shared via articles, seminars, webinars, and event participation

Connected and compliant:

- Demonstrated integration with RTSM, ERP, EDC, and smart medication packages (pill/unit dose tracking)
- Configurable, modular, scalable, and compliant (21 CFR Part 11 and GDPR/HIPAA)

Unified and flexible:

- Delivering enriched patient journeys and site experience throughout the study duration
- Available as a standalone application or can be integrated with other TCS ADD offerings such as e-Consent, Smart Questionnaires, Educational Material, Smart Devices and Wearables and Telemedicine.

TATA CONSULTANCY SERVICES

Awards and accolades

TOP 3 IT SERVICES BRAND

FASTEST GROWING IT SERVICES BRAND FOR THE DECADE 2010 - 2020

About TCS ADD™ Platforms

TCS ADD™ is a modern and open drug development platform for life sciences that enables digital ecosystems, simplifies data complexity and provides faster access to new and effective drugs for patients in need. The platform is powered by our proprietary cognitive intelligence engine data driven smart analytics and Internet of Things (IoT) that makes clinical trials more agile and safe. TCS ADD™ leverages the best of cloud architecture and personalized user experience design in compliance with quality guidelines and privacy regulations.

To know more

Visit https://www.tcs.com/tcs-add on www.tcs.com

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About Tata Consultancy Services Ltd (TCS)

Tata Consultancy Services is a purpose-led transformation partner to many of the world's largest businesses. For more than 50 years, it has been collaborating with clients and communities to build a greater future through innovation and collective knowledge. TCS offers an integrated portfolio of cognitive powered business, technology, and engineering services and solutions. The company's 500,000 consultants in 46 countries help empower individuals, enterprises, and societies to build on belief.

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